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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/677,956
Filing Date: October 01, 2003
Appellant(s): ZEBEDEE ET AL.

Joseph E. Mueth
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 14, 2008 appealing from the Office action mailed August 29, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,350,671	HOUGHTON et al.	9-1994

Weiner et al., "Detection of hepatitis C viral sequences in non-A, non-B hepatitis," The Lancet, vol. 335 No. 8680 (January 1990), pages 1-3.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 141, 143, 144, 146, and 147 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton et al. These claims are directed to a method for the detection of seroconversion associated by NANBV infection (i.e. detection of anti-Hepatitis C virus antibodies in blood serum) at early times after infection comprising the steps of (i) initiating an immunoreaction between a body fluid sample (e.g., blood or blood serum) with an HCV (NANBV) capsid antigen and C-100-3 antigen, (ii) maintaining the immunoreaction for to permit antibodies present in the sample to bind to the antigen to form immunoreaction products, and (ii) detecting the presence of any resulting immunoreaction products. Claims 143 and 144 require the use of a labeled binding agent against the immunoreaction product, particularly where the binding agent is an anti-human IgG. Claim 146 requires that the antigen is affixed to a solid matrix. Claim 147 requires that the capsid antigen is in the form of a fusion protein.

Houghton teaches a method for the detection of anti-HCV antibodies comprising the providing an HCV peptide corresponding to residues 1-84, 9-177, or 1-120 of the sequence in Figure 20 of that reference (each of which includes the sequence of residues 21-40 of SEQ ID NO: 73); contacting the peptide with a biological sample (including fluid samples), and detecting the resulting immunocomplex (the immunoreaction product). See e.g., claims 9-12, and 29. The reference also teaches that the complexes may be detected through the use of labeled binding agents, including anti-immunoglobulin antibodies (claim 32) and demonstrates the use of a labeled goat anti-human IgG antibody (column 98). The reference teaches embodiments where the immunoreaction occurs in an aqueous environment or where the antigen is affixed to a solid support. See e.g., Column 37, and claim 23. The reference also teaches that the antigenic peptides used in the disclosed methods may be in the form of fusion proteins. Columns 27-28. The reference therefore anticipates the indicated claims.

The Houghton reference does not specifically teach the combined use of the antigen described above in combination with the C-100-3 antigen. However, the reference does teach that the C100-3 polypeptide is also useful for the detection of anti-HCV antibodies in samples. See e.g., columns 75-76, 97-98, and 104-105. Because the reference teaches that this peptide would also be useful for the detection of anti-HCV antibodies, it would have been obvious to those of ordinary skill in the art to combine these antigens for the detection of anti-HCV antibodies. This is because it is prima facie obvious to combine compositions known in the art to perform the same function. See e.g., MPEP 2144.06. In addition, it is noted that other teachings in the art indicate that the C-100-3 antigen was known to be useful in the detection of anti-HCV antibodies in serum, but indicates that the use of this antigen alone does not detect every

incidence of HCV infection, thereby providing those in the art with additional motivation to use this antigen in combination with other known HCV antigen.

It is noted that the present claims recite the functional requirement that the claimed method detects seroconversion "at early times after infection." The MPEP indicates in section 2145.II that "[m]ere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention." In the present case, the Appellant has ascribed the ability of the claimed method to detect seroconversion at early times to the use of the capsid antigen. See e.g., the Helting Declaration of January 2007, pages 8 and 9-10. Because Houghton teaches the use of the capsid antigen for the detection of anti-HCV antibodies in serum (claims 1 and 3), this functional requirement would be inherently met by the practice of the invention described by the reference, i.e. it is a latent property of the methods for detecting anti-HCV antibodies described by Houghton.

The teachings of the reference therefore render the claimed methods obvious.

(10) Response to Argument

The Applicant presents nine arguments in traversal of the rejection.

First, the Applicant asserts that the Examiner's application of the Houghton reference fails to render the claimed invention obvious, and is based on improper hindsight. It is noted that no evidence of improper hindsight has been submitted. Moreover, as the rejection relies solely on the teachings found in the prior art, and does not include knowledge gleaned only from the applicant's disclosure, the reconstruction of the claimed invention from the teachings of the prior

art in the present rejection is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The Appellant next argues that the teachings of Houghton do not teach the minimal epitopes or the three dimensional structure of the capsid protein. This argument should not be found persuasive. The present claims are drawn to the use of any HCV capsid antigen. The reference teaches the use of HCV capsid antigens. Moreover, the present application fails to provide any teachings that the use of one capsid antigen provides the functional benefit of detecting early seroconversion, while others do not. Thus, the fact that the Houghton reference does not provide teachings relating to minimal epitopes and three-dimensional structure is not relevant to the present claims as the present claims are not limited to any particular epitope or structure, and as noted by the Appellant on page 9 of the Brief, it is antibodies against the capsid antigen generally, not any particular epitope, that provides the benefit of detecting early seroconversion.

The Appellant next focuses on the failure of the reference to teach that the capsid antigen results in the detection of seroconversion at early times after infection. The Applicant notes the failure of the reference to compare the antigenicity of the core/capsid antigens relative to others disclosed in the reference (for example those of the Figure 65 referenced on pages 13-14 of the Brief.) This argument should not be found persuasive.

It is admitted that the reference does not teach that the use of the capsid antigen enables the earlier detection of anti-HCV antibodies (i.e. early seroconversion). However, as indicated by section 2145 of the MPEP, the case law has indicated that "Mere recognition of latent properties

in the prior art does not render nonobvious an otherwise known invention." As was noted above, the Appellant states on page 9 of the Brief that "the present application revealed for the first time the important benefit to be derived from using capsid antigen which Appellant found to bind to anti-capsid antibodies..., thus providing for detection of HCV seroconversion at early times." In short, the Appellant states that they discovered an new benefit from the use of capsid antigens for the detection of HCV antibodies. However, while they may have discovered this new benefit from using these antibodies, they were not the first to use capsid antigens to detect anti-HCV (i.e. anti-HCV capsid) antibodies. Because they did no more than recognize an additional benefit from the use of the antigens in a method described by Houghton (see e.g., claim 1), the Appellant has failed to rebut the prima facie case of obviousness.

Appellant's third set of arguments regard the lack of a showing of detection of early seroconversion in the results of Figure 65 of the Houghton reference. It is noted that the Appellant's arguments are based on conjecture. The Appellant has made assumptions with respect to the experimental design that arrived at those results, and with respect to how the figure would have been interpreted by those in the art based on that hypothetical design. In view of the lack of any evidence in support of their interpretation of the figure, Appellant's arguments that those in the art would have considered the figure to teach away from the use of the capsid antigen for the detection of seroconversion at early times after infection should not be found persuasive.

Appellant's fourth argument is directed to the "very immunogenic" terminology referenced on pages 17-18 of the Brief. This argument is not understood. Nothing in the Examiner's statement of the rejection refers to this terminology, and it does not form the basis of the rejection. Thus, Appellant's arguments with respect to this language should not be found persuasive.

Appellant's fifth set of arguments, found on page 18 of the Brief, relate to the insufficiency of the false negatives problem in the use of C-100-3 alone as providing motivation for the combination of the capsid antigen therewith. This argument should also not be found persuasive. This is because this problem to be resolved is not the primary basis on which the rejection relies for the combination. The teachings of Houghton indicate that both the C-100-3 and the capsid antigens are useful for the detection of anti-HCV antibodies. In addition, Houghton specifically teaches the use of the capsid antigen for the detection of anti-HCV antibodies in serum (see e.g., claims 1 and 3), while the art (as represented by Weiner et al.) indicates that the C-100-3 antigen was also recognized in the art as useful for such detection of anti-HCV antibodies. According to the MPEP (section 2144.06), it is "*prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose." It would therefore have been obvious to those of ordinary skill in the art to have combined the capsid antigens disclosed by Houghton with the C-100-3 antigens for the purpose of detecting anti-HCV antibodies.

Thus, while the resolution of the false-negative problem with respect to the C-100-3 antigen may not have alone provided adequate motivation for the combination (although it noted that such teachings at least indicate that those in the art would not be disinclined to combine this antigen with other HCV antigens) for the specific combination of the capsid antigen with the C-100-3, this is not the primary basis for motivation to combine being relied on in the rejection. The Appellant's arguments on this basis should therefore also not be found persuasive.

The Appellant further asserts on page 27 of the Brief that the failure of the Houghton reference to teach the problem with the use of the C-100-3 antigen negates a finding that it would have been obvious to those of ordinary skill in the art to resolve the problem by making the combination claimed. This argument should not be found persuasive because those of ordinary skill in the art are not limited to the Appellant's motivation for making the combination. As was indicated above, the motivation for the combination is not found in the failure or limitations of the C-100-3 antigen, but in the common utility of the C-100-3 and capsid antigens. Any additional benefit arrived at from the combination would be a latent property/ previously unrecognized additional advantage (as per MPEP 2145.II) of the obvious invention. As was described above, such additional benefits do not render an otherwise obvious invention non-obvious.

The sixth argument presented by Appellant asserts that there is nothing in the Houghton reference to specifically suggest the combination of capsid antigens with the C-100-3 antigen should also not be found persuasive. There is no requirement that such a specific teaching be presented in the art. The U.S. Supreme Court specifically stated such in its 2007 decision in *KSR*

International v. Teleflex Inc. 82 U.S.P.Q.2d 1385, at 1389 (specifically rejected the teaching, suggestion, motivation test for obviousness as the sole basis for finding an invention obvious). Rather, in that decision, the court specifically indicated that the combination of two elements to perform the same as they would separately, and without creating some new synergy, was obvious. Id., at 1395. In the present case, the Appellant has merely combined two elements, each known to be useful for the detection of anti-HCV antibodies, for use in a method for the detection of such antibodies. The Appellant has demonstrated no synergy that results from the combination. The additional benefit seen from the use of the capsid antigen alone has not been shown to synergize with the antibody binding properties of the C-100-3 antigen, or any other anti-HCV antigen. Because this case relates merely to the combination of elements known in the art for use in a common function, and as no synergy has been shown with respect to the combination, no specific teaching suggesting the combination of the specific antigens is required. The argument to the contrary should therefore not be found persuasive.

Appellant's seventh argument, with respect to the "focus on C-100, CA 279 and CA 290" is also not understood. There has been no such focus on these antigens except insofar as the claims are directed to the use of C-100-3. It would have been obvious from the teachings of Houghton to have combined any of the antigens identified as useful for the detection of anti-HCV antibodies to be used in a combined method for that purpose.

Appellant's next set of arguments, with respect to the reasonable expectation element of the obviousness rejection is noted. Brief, pages 21-24. However, the Applicant has not explained

its relevance to the present case. There is no argument or evidence that the combination of the C-100-3 and capsid antigens would not have been reasonably expected by those of ordinary skill in the art to operate for the detection of anti-HCV antibodies. Thus, the argument is not clear, and should not be found persuasive.

Further, there is no requirement in the present rejection to show that there would have been a reasonable expectation that the claimed method would result in the claimed benefit of detecting early seroconversion. This is for two reasons. First, the rejection does not rely on such a showing. Second, according to the Appellant's own argument on page 9 of the Brief, this benefit would achieved by any method in which an HCV capsid antigen was used to detection anti-HCV antibodies. Because the rejection is on the basis that the claimed method itself would have been obvious, and that the effect of being able to detect early seroconversion is no more than a recognition of a latent advantage of that obvious method, there is no need for the Examiner to demonstrate that those of ordinary skill in the art would have had a reasonable expectation that the method would have achieved that functional effect.

For each of these reasons, Appellant's argument with respect to the "reasonable expectation of success" element of the rejection should not be found persuasive.

Appellant's eighth argument is an assertion that the Examiner is wrong in his conclusion that it is the use of the capsid antigen alone that results in the asserted unexpected results of being capable of detecting HCV seroconversion at early times. It is not understood how the Appellant can make such an assertion where the arguments of the Brief open at page 9 by stating

that it is the use of the capsid antigens that results in the ability to detect early seroconversion. This argument should therefore not be found persuasive.

Finally, Appellant argues on page 28 that the Petition to Make Special evidences the commercial importance of the claimed invention. It appears that this is an assertion of another form of secondary evidence of non-obviousness. However, it is noted that the indicated petition does no more than show potential infringement of the claims desired by the Appellant. It shows no commercial success or other commercial significance that shows any connection with the obviousness of the claimed invention. I.e., no nexus has been shown between this asserted commercial importance and the obviousness of the claimed invention as is required by MPEP 716.01(b) in arguments relating to secondary evidence of non-obviousness. This argument should therefore also not be found persuasive.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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